

# Aligning Healthcare Professional and Patient Education: *Challenges and Risks*

Presented by the MAPS External Education and Compliance Focus Area Working Groups



## >> NOW SPEAKING: **Kirtida Pandya, PharmD, Moderator**

Executive Director, Medical Services and Operations, Sandoz

# Introductions



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Moderator

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# Housekeeping

### Questions for Presenters

Please submit questions throughout the presentation using the Q&A button in your control panel.

### Evaluations

The control panel includes a webinar evaluation. Please complete this evaluation so that we can work to ensure the highest quality presentations.

### On-Demand Availability of Webinar

This webinar and corresponding PowerPoint, as with all previous ones, will be available on demand next week via the MAPS website Content Hub.



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# Webinar Objectives

**At the end of today's webinar, participants will have a better understanding of:**

- The approach of aligning HCP education with patient education to optimize patient and healthcare outcomes
- The different types of aligned HCP and patient education models
- The risks and challenges of providing aligned HCP and patient education that is transparent, fair, and lawful



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# Webinar Agenda

- 01** Welcome and introduction
- 02** Landscape assessment
- 03** Medical Affairs support for aligned medical education
- 04** Risk mitigation: transparency, fairness, and lawfulness
- 05** Open Q&A
- 06** Closing thoughts
- 07** Close

# Landscape Assessment



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## Polling Question 1



**Question for audience:** In your organization, how has level of educational support for patients changed in the last 18 months?



More



Same



Less



A lot less





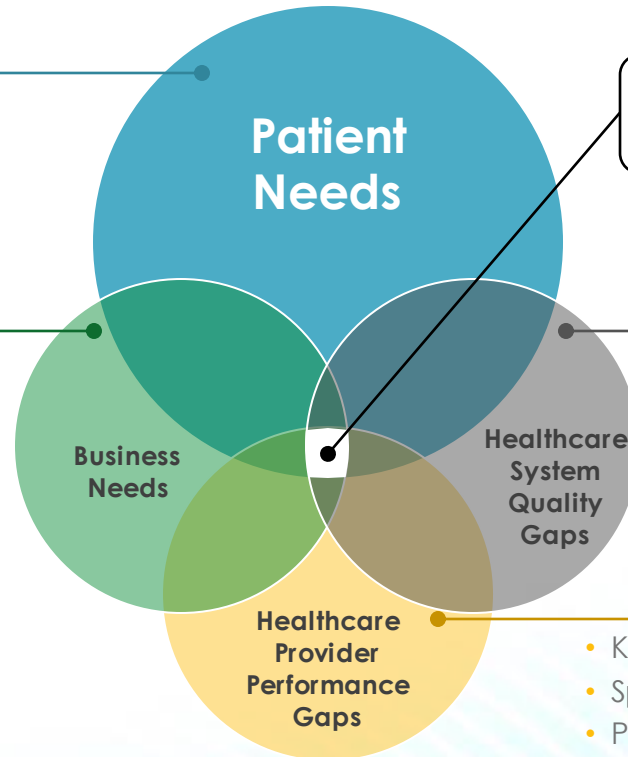
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Director Medical Education Excellence, AbbVie

## Patient Needs Are at the Core of Industry Education

- Adherence to treatment plans
- Social/cultural barriers
- Access to care/cost
- Understanding of disease

- Disease areas
  - Underdiagnosis
  - Appropriate and safe product use
- Mechanism(s) of action
- New or emerging data
- Product life cycle variables
- Insights gathering, data gaps



Overlapping area of mutual value

- Quality measures
- Prevalence
- Incidence
- Guidelines
- Cost/reimbursement/value
- Systems variables
- Social determinants of health

- Knowledge, skills, and attitudes
- Specialty
- Practice setting
- Standards of care

Based on Saxton M. J Contin Educ Health Prof 2009;29:71–5. Institute of Medicine (US) Committee on Planning a Continuing Health Professional Education Institute. Redesigning Continuing Education In the Health Professions. Washington, DC: National Academy Press (US); 2010.



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# What Do We Mean by Patient Education?

Enabling individuals to participate in their healthcare by:

- **Managing** the physiological and psychological consequences of their healthcare
- **Solving** problems and **making decisions** about healthcare management
- **Promoting health** and **disease prevention**
- **Becoming a partner** with healthcare professionals





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# Increased Emphasis on Patient Education



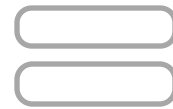
Population growing older, more chronic disease population, and sedentary lifestyle



Increased pressure on health systems and recognition of healthcare disparities



Increased availability of information and digital access, and more empowered patients



Patient education



Improved patient outcomes and disease management



Fewer complications, hospitalizations, clinic visits



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# Patients Are More Engaged in Their Health

WHO defines empowerment as “a process through which people gain greater control over decisions and actions affecting their health” (WHO 1998)



## 1. Information Availability

Information is fundamental to the process of patient empowerment.



## 2. Health Literacy Has Improved

While access to information is a key driver of patient information, health literacy is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”



## 3. Digital Literacy Has Improved

Cornell University defines digital literacy as “the ability to find, evaluate, utilize, share, and create content using information technologies and the Internet.”



## 4. Increase Perception of Self-Efficacy

Self-efficacy, as it relates to healthcare, is belief in your ability to effect change in outcomes so that you can achieve your personal health goals.



## 5. Enhance Shared Decision-Making

This partnership approach allows for Shared Decision-Making (SDM).



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# MA Educational Types Involving Patients and HCPs



HCP



Patient



HCP Education Includes Patient Voice	Simultaneous HCP and Patient Education	Sequential Patient and HCP Education	Direct Education for Patients Only
<p>The patient voice is integrated into the HCP education.</p> <p>This can be done through having a patient present live/online at the event or through case vignettes developed through patient interviews.</p>	<p>HCP and patient components are launched independently of each other.</p> <p>This type of support ensures that the topics are aligned.</p>	<p>The patient education component is separated and distinct. It can be launched prior to the HCP component or after.</p> <p>Patient insights are used to inform the development of the HCP component or vice versa.</p>	<p>Can be delivered directly to patients or delivered indirectly through HCPs.</p> <p>This education can include development of resources for shared decision-making and/or treatment options.</p>



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# Stakeholders



## Pharma Industry

- Medical Affairs
- Commercial
- Corporate Affairs
- IME Grant Office
- Medical Information



## External Organizations

- Academic and Integrated Health Networks
- Hospitals
- Meeting Planning Organizations
- Medical Professional Societies
- Patient Organizations



## Education Recipients

- Healthcare Professionals
- Patients
- Caregivers
- Families

# Medical Affairs Support for Aligned Medical Education



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## Polling Question 2



**Question for audience:** What type of patient education does your organization support or develop? (Multiselect option)

- HCP education that includes the patient voice
- Simultaneous HCP and patient education
- Sequential patient and HCP education
- Direct education for patients only



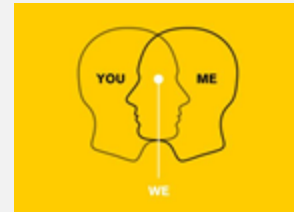


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# HCP Education Includes Patient Voice

## Rationale

- Raise HCP understanding and empathy for patient's unmet needs and QoL
- Reduce diagnostic delay
- Improve comorbidity management
- Improve HCP-patient communication
- Focus on personalized treatment



Motivational Interviewing



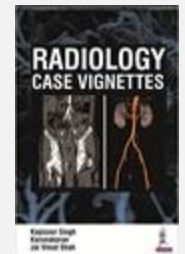
Empathy Videos



Diagnostic Support Tools



Patient Panel Discussion



Case Vignettes



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# Simultaneous Patient and HCP Education

## Rationale

- HCP and patient receive education on the same topic at the same time
- Improve HCP–patient communication
- Raise HCP and patient interest regarding unmet needs
- Address barriers simultaneously



Patient and  
HCP Webinars



Printed Aid  
Materials



Websites



Conferences



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# Sequential Patient and HCP Education

## Rationale

- Gain patients' perspectives to inform HCP education or vice versa
- Identify and address patient barriers and challenges for inclusion in HCP education or vice versa
- Address most impactful gaps first



QoL, Pain Points  
Surveys



Communities of  
Practice



Reputable Website  
Resources



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# Direct Education for Patients Only

## Rationale

- Raise awareness of diseases and standards of care
- Gaps may only apply to patients (e.g. treatment adherence)
- Empower patients to participate in their care



Websites



Materials

- Checklist for communication
- Mythbusters



Communities of Practices



Webinars



Care Apps

# Risk Mitigation: Transparency, Fairness, and Lawfulness



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## Polling Question 3



**Question for audience:** Do you have policies and procedures for medical education and patient education?

**A**

Policies and procedures for medical education but no formal procedures for patient education

**B**

Separate policies and procedures for medical education and patient education

**C**

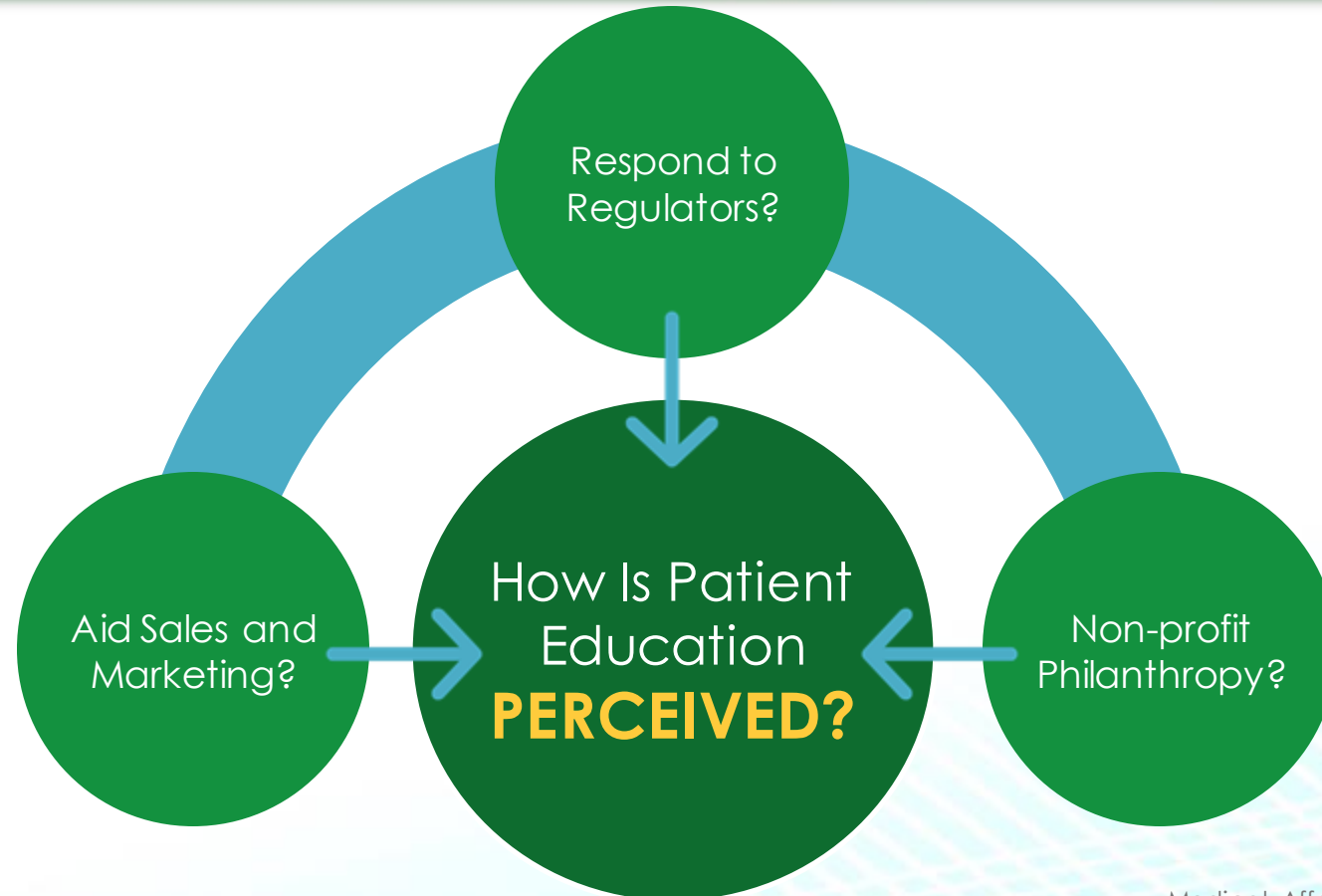
Policies and procedures that include both medical education and patient education



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# Risk Mitigation – Perception

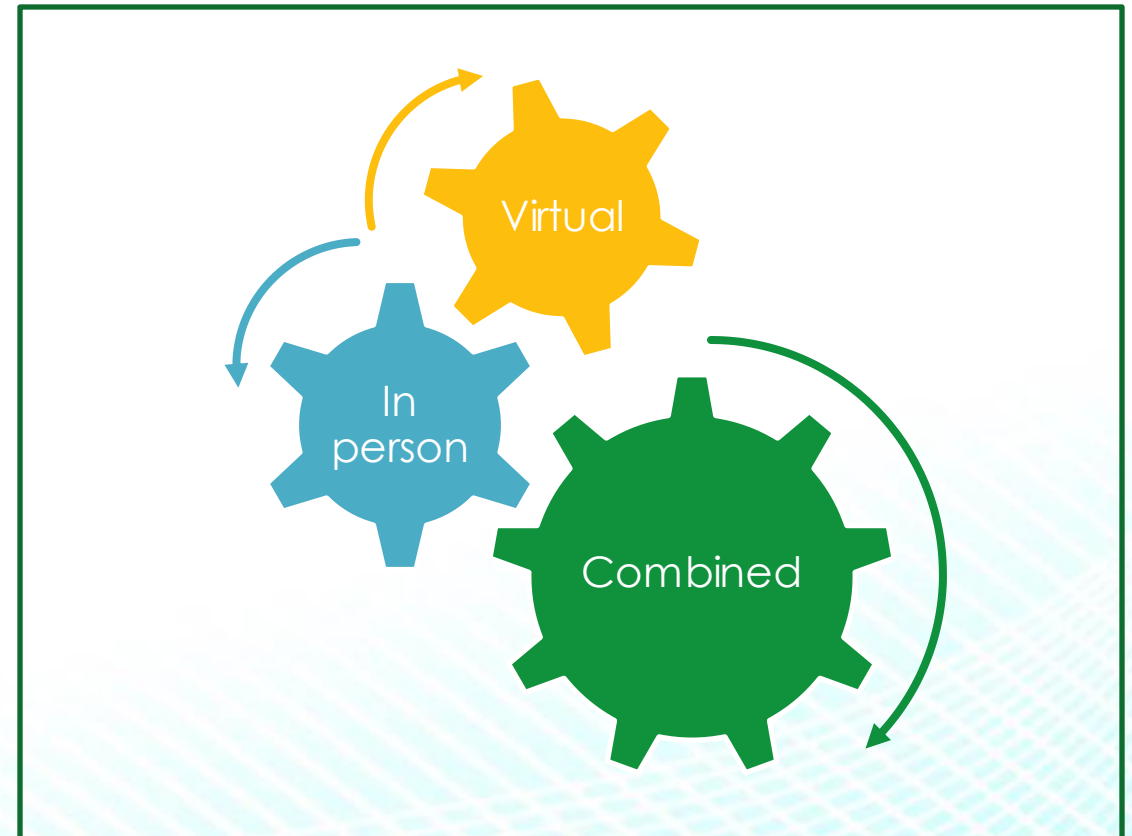
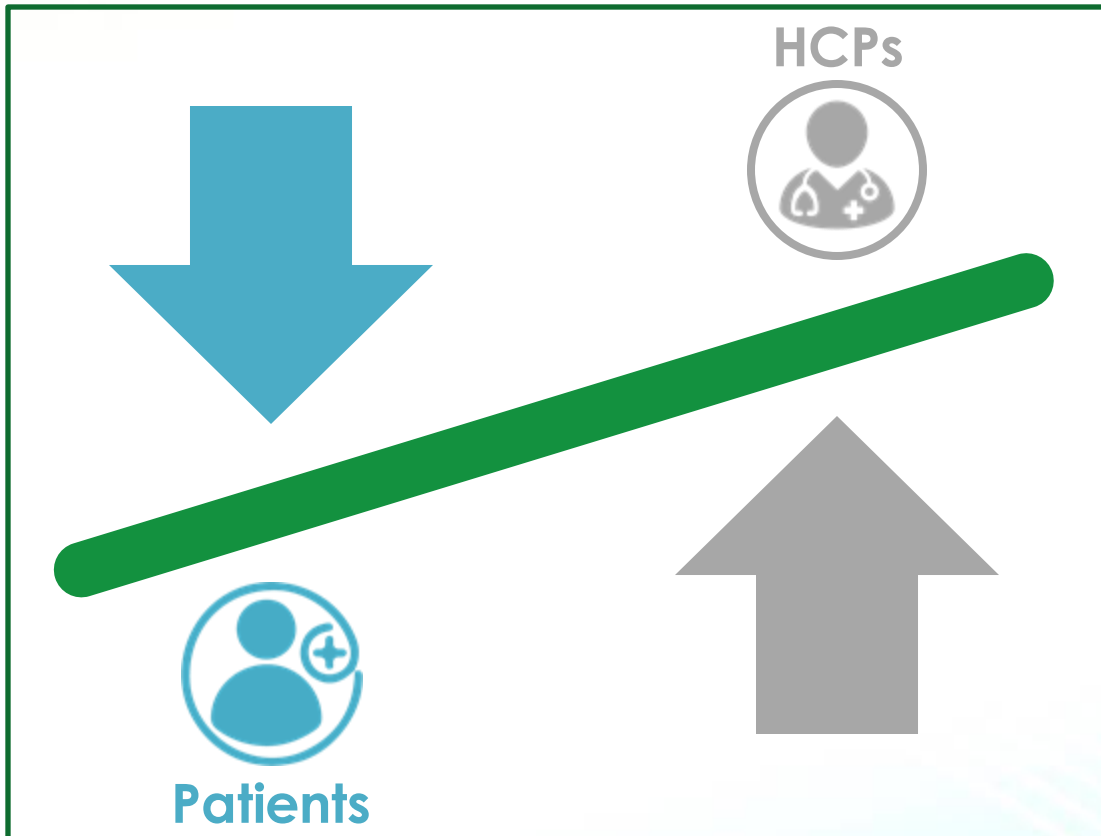




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# Risk Mitigation – Audience and Control



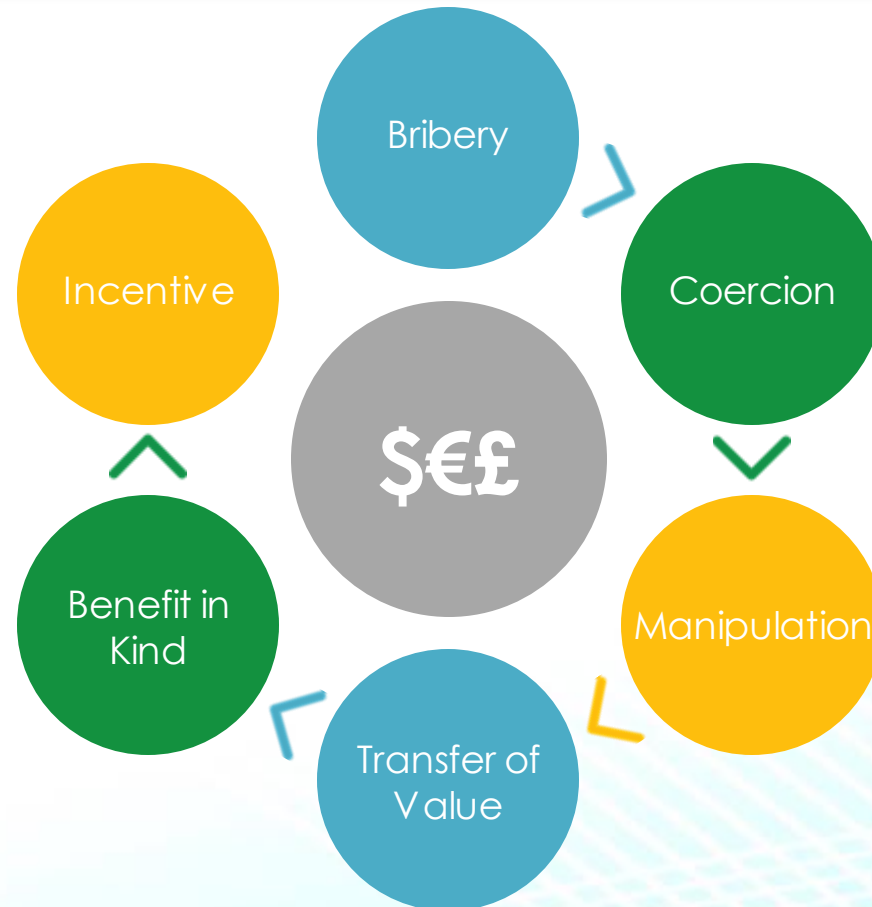




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# Risk Mitigation – \$€£...





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## Risk Mitigation – Which Standards?



- Demand from regulators and established standards
  - Pharmaceutical trade associations' codes and regulations (e.g. IFPMA, EFPIA, PhRMA, RDPAC, JPMA)
  - Accreditation standards (global, regional, local)
  - Government/regulatory requirements, e.g.
    - US FDA, ACCME, OIG (Office of Inspector General)
- Disparities in expectations of program outcomes
- No true standards in integrated program design and quality across countries and regions
- No global implementation of integrated medical education HCP/patient education (CME/CPD/IPE) standards across healthcare disciplines



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# Risk Mitigation – Interaction with Patients or Patient Organizations



- Company compliance policies for interactions with patients and patient organizations
- Are other parts of the organization/company also funding patient education via donations (e.g. Corporate Affairs, Patient Office)?
- Learnings from other interactions with patient organizations that are considered high/low risk
  - Industry support to co-pay foundations
  - Industry manufacturers of opioid products support for not-for-profit organizations



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Independent Consultant

# Define/Leverage Existing Policies and Procedures



- 1  
2  
3  
Company sponsored – the educational message is on label?  
Were the materials evaluated through a medical review committee?
- 1  
2  
3  
Independent education – adhere to relevant accreditation requirements, industry codes, and local regulations
- What functions are part of the governance? What functions must be excluded?
- 4  
5  
If relevant, was the budget aligned with fair market value? Is there a contract in place?  
Were the appropriate screening and debarment checks executed?
- Confirmation of who attended. Full transparency/disclosure. Confirmation of the proposed outcomes



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## Risk Controls \$€£... Follow the Money



- Ensure transparency for any transfer of value (money)/benefit in kind (e.g. tax reduction)
  - Transparency regarding who developed the material and the funding of not-for-profit and for-profit organizations
    - Transparency regarding aligned HCP/patient education on company websites
    - Transparency/Disclosures of funding at the program/event and on any materials
    - Disclosure of funding on national websites
  - Consider identifying funding as a patient education grant vs a charitable donation



- Who can support the aligned/integrated HCP/patient education?
  - Development of company-led education
  - Funding of independent education
  - Is it only Medical Affairs?



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## Risk Mitigation – Privacy



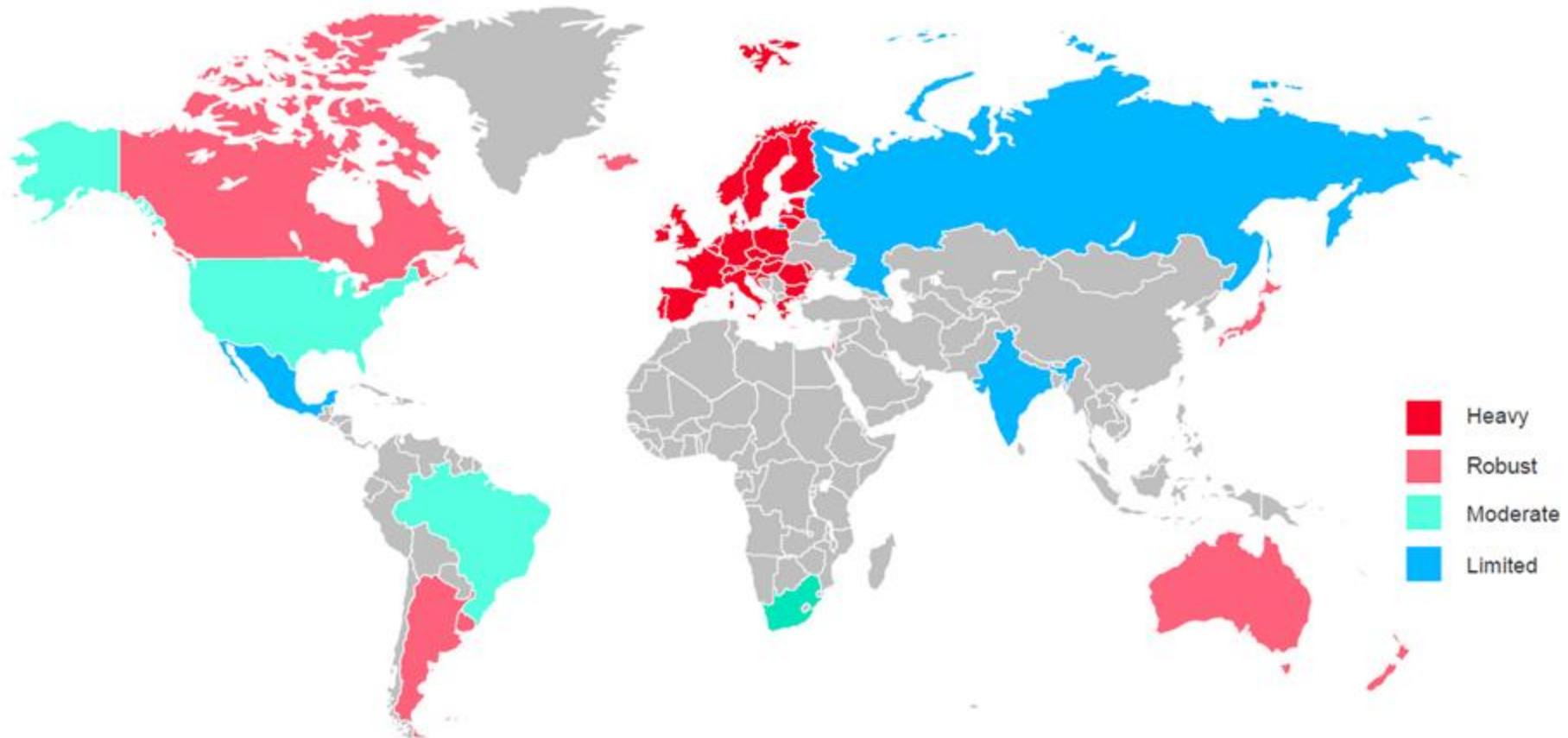
- Expanded privacy legislation in the world (GDPR, CCPA, CPRA, LGPD, etc.)
- Healthcare data are often classified as sensitive data or special category data
- Use patient voice in HCP education
- Use patient voice in public domain
- Patients use patient education materials



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# Privacy Regulatory Landscape in 2010

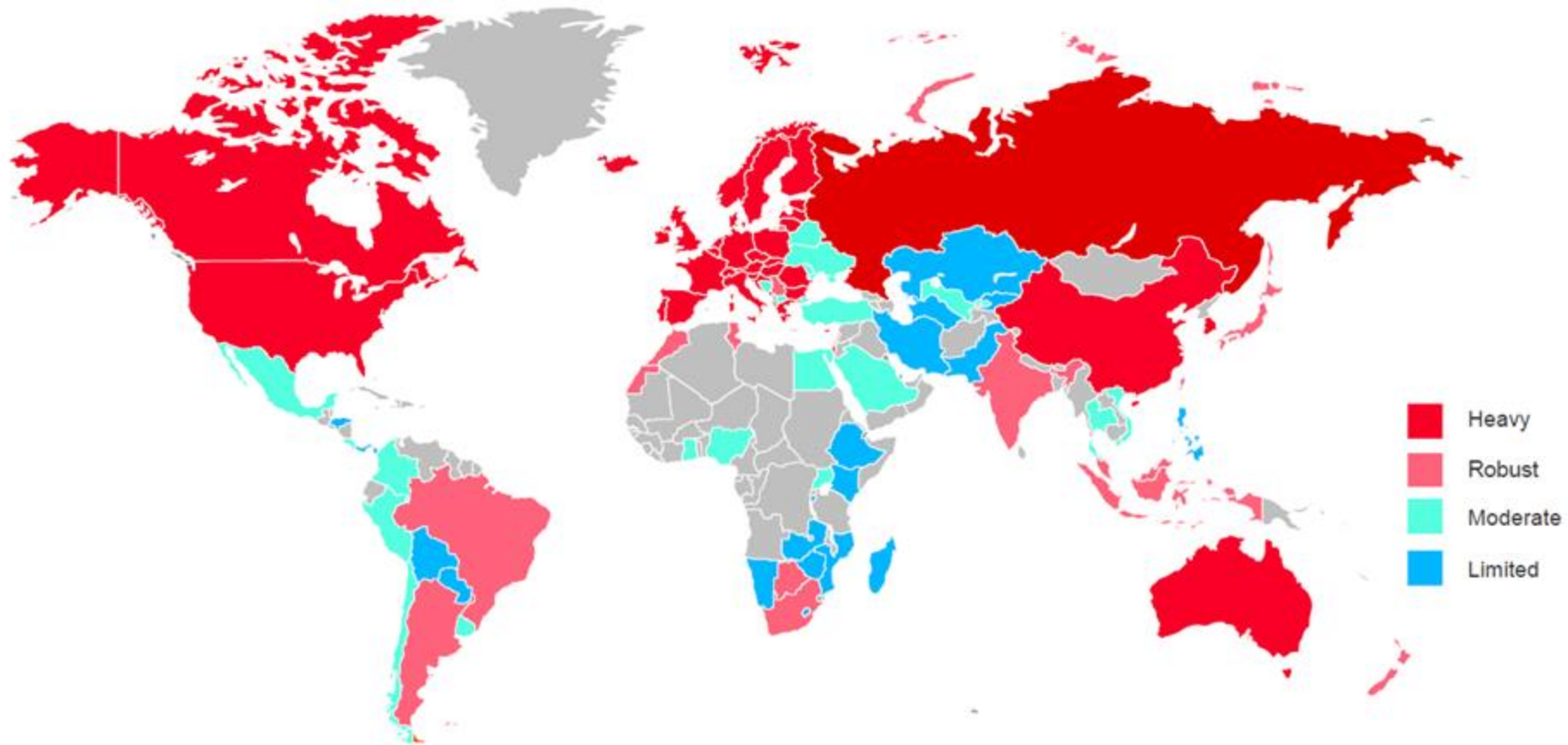




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# Privacy Regulatory Landscape in 2021



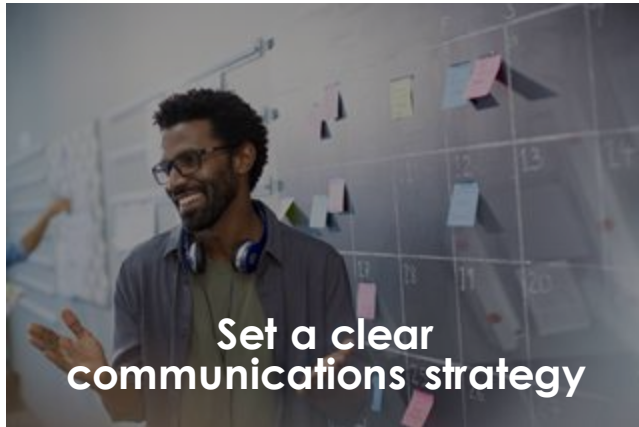




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# Practical Tips/Compliance Considerations



- Define communication/information-sharing strategy **internal and external**
- Training, communication materials



- Assess risks with respect to (i) regulatory requirements, (ii) healthcare compliance
- Define the key compliance controls to mitigate risk



- Integrate monitoring into the initial implementation of aligned education
- Conduct voluntary internal audit(s) 12 to 18 months after implementation of procedures



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# Questions to Ask When Considering Aligned HCP and Patient Education

Whether the aligned/integrated HCP and patient education is independent or company developed:

- Consider the rationale and the benefit v risks
- Implement controls to manage the risks

**3** Does the alignment of HCP and patient education add value to addressing a medical need/gap?

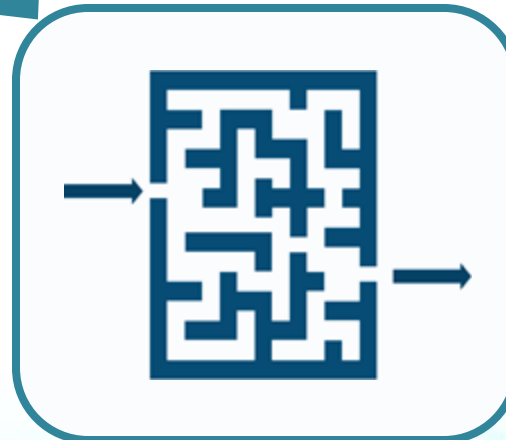
**2** Does the education address a recognized need/gap?

**1** Is the proposed education aligned with medical and education strategy

**4** Are there local regulations or industry standards/professional societies that need to be addressed?

**5** What are the proposed outcomes? Do they address both the HCPs and the patients?

**6** What are the requirements for transparency & disclosure including on public website(s)?



**Thank You!**  
*Questions?*